Attorney Docket No.: 3486-018

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	HOCHMAN, Mark N.
Serial No.:	:	09/745,751
Filing Date	:	December 21, 2000
Title	:	METHOD FOR PERFORMING AN INJECTION USING A BI-DIRECTIONAL ROTATIONAL INSERTION TECHNIQUE
Examiner	:	HAYES, Michael J.
Group Art Unit	:	3763

DECLARATION BY INVENTOR UNDER 37CFR 1.131

I, Mark Hochman, make the following declaration in support of the subject application:

1. I am the inventor of the subject application.

2. In the Office Action of July 3, 2003, the Examiner has rejected the claims as being anticipated by, or obvious in view of U.S. Patent No. 6,258,064 (Smith et al) which issued on July 10, 2001, based on an application filed on October 4, 1999.

3. The present application claims priority to provisional application 60/173,374 filed December 28, 1999.

4. Prior to October 4, 1999, I have invented and reduced to practice a method of

administering drug to a patient comprising the steps of:

providing a needle associated with a drug supply, said needle having an elongated shaft, a lumen and a beveled tip with an exit point communicating with said lumen, said drug being selectively ~~so that said drug is~~ forced from said drug supply through said lumen and out of said exit point;

advancing said needle along a longitudinal axis of the needle through the patient tissue until a predetermined site is reached; and

simultaneously rotating said needle about said longitudinal axis during said advancing to prevent said needle from being deflected.

5. Prior to October 4, 1999, I have invented and reduced to practice a method of administering drug to a patient comprising the steps of:

providing a needle associated with a drug supply, said needle having an elongated shaft, a lumen and a beveled tip with an exit point communicating with said lumen, said drug being selectively forced from said drug supply through said lumen and out of said exit point;

advancing said needle along a longitudinal axis of the needle through the patient tissue until a predetermined site is reached; and

simultaneously rotating said needle about said longitudinal axis during said advancing to prevent said needle from being deflected.

6. Prior to October 4, 1999, I submitted an early draft of an article to a publication entitled Quintessence International. I believe that this early draft was identical to the document attached hereto as Exhibit A. This document was subsequently filed as the

provisional application and it describes in detail the experiments were performed as part of my reduction to practice of the invention.

7. Prior to October 4, 1999, I received a letter from William F. Weathen, DMD, Editor-in-Chief of Quintessence International, indicating that the draft (or manuscript) "can be considered for publication." A copy of this letter without the attachments is attached hereto as Exhibit B . (The attachments contain comments from various reviewers).

8. In response to the letter from Weathen, article was redrafted and it was published in 2000. A copy of the article is attached as Exhibit C.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Mark Hochman

Date: 9/23/03

Exhibit A

Res arch manuscript

Title:

In-Vitro study of needle deflection: A linear insertion vs. bi-directional rotation insertion technique.

Abstract

Title:
<u>In-Vitro study of needle deflection: A linear insertion vs. bi-directional rotation insertion technique</u>

Deflection of dental needles during tissue penetration has been associated with a failure to achieve successful anesthesia. Dental needles of various diameters (gauges) have been shown to deflect in a direction opposite to the bevel. A new technique has been introduced to minimize the amount of needle deflection, a bi-directional rotation insertion technique. This technique was found to reduce deflection for the three needles tested in a variety of tissue-like substances. The ability to maintain a straighter path toward the intended target may lead to a higher success rate for those injections which require deep tissue penetration, such as the inferior alveolar block.

Version 1.09

INTRODUCTION:

Successful local anesthesia is critical to the daily practice of dentistry, as it is a prerequisite to performing the majority of our clinical procedures in both comfort and safety. Predictability in obtaining a positive result is, therefore, of great importance to the practicing dentist. The most significant factors identified as influencing successful anesthesia include: patient anatomical variations, improper operator technique and the physical characteristic of needle deflection[1,2].

Needle diameter (gauge) and the degree of flexibility or resilience of the needle shaft are associated with the physical characteristic of needle deflection[3]. Early studies that utilized a static flexibility model did not take into account the effect of bevel design and the forces that are created during substance penetration [4,5,6,7,8]. These studies are responsible for establishing a belief that shaft diameter is a critical factor leading to needle deflection.

Aldous[9] was the first investigator to approach the evaluation of needle deflection with a dynamic testing method that more accurately portrayed the clinical situation. He incorporated the use of a dental surveyor that standardized the direction of the injection force. Materials with consistent densities were selected to represent tissue-like substances. Needle deflection was recorded on radiographic film when the needle was inserted into the tested material. He concluded that needle diameter was inversely related to the amount of deflection produced by a given needle. He also stated that the shape and angle of the bevel affected the degree of deflection.

Robinson and coworkers[10] improved upon Aldous's original study design by evaluating needle deflection geometrically in two planes of space. Radiographs were taken at perpendicular angles, allowing for a more precise needle deflection analysis. He concluded that all beveled needles produce deflection, and the amount cannot be correlated to the gauge of a needle. Robinson suggested that needle deflection was related more to the type of metal selected for manufacturing than the actual gauge of the needle, however this hypothesis has not been substantiated by any other author.

Jeske and Boshart[11] tested a unique needle bevel design using the same testing model Aldous described. The needle tested was beveled on two opposite sides of the shaft, placing the needle tip at approximately the center of the long axis. They concluded that needle tip design is more critical to reducing and eliminating deflection than the diameter of the needle.

A controversy exists in the literature regarding the factor responsible for producing needle deflection. This study was conducted to determine whether needle deflection could be minimized using a bi-directional rotation insertion technique. A second objective was to determine whether needles of different gauge responded differently to the introduction of a bi-directional rotation insertion technique during placement into a tissue-like substance. A final objective was to determine which factors most greatly influence the magnitude of needle deflection.

Materials and Methods:

The authors describe a new needle insertion technique designed to overcome the undesirable effect of needle deflection. This technique seeks to produce a more accurate, straight-line needle tracking through substances regardless of needle gauge. It utilizes a pen-like grasp in which the needle is rotated approximately 180° in a back-and-forth motion, between the thumb and index finger. The type of rotation used is analogous to techniques that have been described for endodontic file instrumentation and acupuncture. This bi-directional rotation action is maintained throughout needle advancement. The study design followed a protocol by Robinson, et al[12].

Three deflection test models were constructed. The test models differed in the tissue-like substances that were used. In each of the three models the needle was inserted to a depth of 20 mm. The following materials served as tissue-like substances in this study, Hydrocolloid (test model A), frankfurters (test model B), and soft bitewafer wax (test model C). All three tests utilized a dental surveyor (Ney) to produce uniform needle insertion. (see fig. 1) With each tissue-like substance three different size needle gauges were tested (30-gauge - 1 inch; 27 and 25 gauge - 1¼ inch). Screw mount needle hubs were attached to a customized arm of the surveyor. The needle was then advanced into the tissue-like substance using either the test technique - a bi-directional rotation insertion movement, or the control technique – traditional insertion using a linear non-rotational insertion

Deflection test model A: Reversible Hydrocolloid (Acculoid™ Extra Strength, Van R Dental Products, Inc. Product # 11110) was placed into a 6 oz. plastic container which fit into the custom surveyor jig . The jig was constructed to produce consistent

perpendicular angulation of the x-ray tube head. The custom jig was designed to record needle deflection in two planes of space fixed at 90 degrees from each other. (see fig. 1) This enabled the total amount of deflection to be calculated from an algebraic formula. A total of 60 insertions were performed using 30 needles (10 needles for each needle gauge size).

Each needle served as its own control between the two techniques. Each needle was first inserted into the tissue-like substance with a linear non-rotating movement. The same needle was next inserted into the test material using the bi-directional rotation insertion technique. After the needle was used for the second insertion technique it was discarded and the test redone using a new needle.

After each needle insertion two x-ray films were exposed at 15MA, 65 KVP, and 10 impulses and developed. A metallic x-ray grid was used to record the maximum amount of deflection produced. Each film was measured with a Boley gauge on a superimposed grid from the point of insertion to the tip of the needle. The total amount of deflection produced was calculated using a geometric principle as described by Robinson and co-workers[13].

Deflection test model B: A second tissue-like substance deflection test was performed on processed meat, frankfurters (Hebrew National, Inc.). The identical protocol test model A was followed. A total of 42 insertions were performed using 21 needles (7 needles for each needle gauge size).

Deflection test model C: A third tissue-like substance deflection test was performed on soft wax bitewafer's (The Hygenic Corp. Akron, Ohio.). A custom

platform was constructed which aligns the wax parallel to the long axis of the needle held by the dental surveyor arm. The use of soft wax bitewafer allowed for visual inspection to determine and measure the amount of needle deflection observed.

Orientation of the needle bevel was perpendicular to the surface of the wax, this was confirmed by the operator wearing magnification loops (Designs for Vision, Inc.). First, the needle was inserted to a depth of 20 mm into the wax using a non-rotational linear movement. Total deflection of the needle was identified by marking the wax at a point were the needle tip ended within the wax bitewafer. The needle was removed from the wax and positioned in front of the wax with the shaft of the needle aligned with the access hole created from the initial insertion. The needle was lowered 20 mm, and a Boley gauge was used to measure the distance of deflection that was observed. The same needle was employed for the second test (bi-directional rotation insertion technique) into the wax bitewafer. Each needle therefore served as its own control. A total of 100 insertions were preformed using 50 needles of a 30 gauge size. An additional 40 insertions using 10 needles each of 27 and 25 gauge was conducted to compare the two techniques. The needles used for the study were randomly selected from a standard box of 100 needles (Monojet, Inc.) as supplied by a local dental distributor.

RESULTS:

The study design involved repeated sets of three experiments comparing needle deflection for the two techniques of needle insertion for a particular needle gauge in different injection mediums. Statistical data analysis was performed by Paired T-tests for each experiment. The rotational technique described was consistently more effective in

minimizing needle shaft deflection for a 30 gauge, 27 gauge and 25 gauge needle. Each of the different tissue-like substances tested consistently demonstrated this reduction in needle deflection with the bi-directional rotation insertion technique.

Differences in deflection between linear and rotational insertion were found to be statistically significant ($P<.05$) in each of the experiments conducted. A 95% confidence level with no overlap of the upper and lower limits was observed.

When comparing linear insertion to bi-directional rotation insertion the mean amount of total deflection of a 30 gauge needle in wax was 2.7 mm vs. 0.1 mm respectively. In hydrocolloid the total mean deflection was 4.7 mm vs. 1.1 mm comparing linear to rotational insertion. In frankfurters the total mean deflection between linear and rotational insertion was 2.2 mm vs. 0.2 mm.

The comparison of linear to bi-directional rotation insertion technique for a 27 gauge needle was as follows: total mean deflection in wax was 3.4 mm vs. 0.1 mm, in hydrocolloid was 4.6 mm vs. 0.8 mm, in frankfurter was 1.4 mm vs. 0.6 mm respectively.

The comparison of linear to bi-directional rotation insertion technique for a 25 gauge needle was as follows: total mean deflection in wax was 2.6 mm vs. 0.1 mm; in hydrocolloid 3.8 mm vs. 0.5 mm; in frankfurter 0.9 mm vs. 0.2 mm respectively.

Discussion:

It has long been suggested that all needles deflect irrespective of the diameter of the needle being used. Aldous was the first to devise a dynamic testing method in which he concluded that needle deflection was inversely related to needle diameter[14]. Robinson and co-workers, used a testing model which added a more accurate deflection recording

method, concluded that all needles (25, 27 and 30 gauge) deflected[15]. Robinson stated that the degree to which a needle deflects is not related to the diameter but may be more related to the metal chosen during the manufacturing of a needle.

A previous study has shown that bevel design at the tip of a needle will influence the passage through various substances[16]. It is apparent that a force vector system is produced on the surface of the needle bevel which would be similar to any cylindrical object with a beveled end. This vector force system follows the laws of physics in accordance to Newton's third law of equal and opposite forces. Therefore, an application of a resultant vector of force upon this eccentric beveled point at the end of a cylindrical shaft will produce the physical finding of bending (deflection) along its path of insertion. (see fig. 2) The amount of deflection experienced by this beveled cylindrical object is determined by its design and the response of the forces within the given insertion medium.

A bi-beveled needle has the advantage of possessing a needle tip which is centrically located along the needle shaft. Testing of this needle design produced study results showing reduced needle shaft deflection[17,18]. The bi-beveled needle eliminates those perpendicular forces that produce the needle shaft deflection which is seen clinically.

Use of the bi-directional rotation insertion technique with an eccentric pointed bevel needle allows the operator to cancel out the perpendicular vectors of forces along the shaft of the needle. (see fig. 3) This helps to generate a final resultant of forces acting on the bevel to move in a more linear path of travel. This straighter path of needle movement is unrelated to the size of the needle (gauge), the material selected for manufacturing, or the specific needle bevel design.

The traditional handheld syringe which requires a palm-thumb grasp does not lend itself easily to incorporation of the rotational insertion technique. This may explain why this technique has not been described in the past. A recently introduced anesthetic delivery system (The Wand™, Milestone Scientific Inc.) was designed with a disposable hand-piece which requires the operator to use a pen-like grasp. The benefits of a bi-directional rotation insertion technique can be maximized with a pen-like grasp.

The density of the medium into which a needle is inserted appears to influence the amount of deflection produced by the beveled needle. Tissue-like substances with greater density, ie hydrocolloid, consistently produced greater deflection compared with less dense substances. However, the technique of insertion being used was shown to have a greater influence on whether deflection was produced by each needle.

Needle length appeared to be another factor which influenced the amount of deflection. The finding of increased needle deflection of 27 gauge needles compared to 30 gauge needles in the denser tissue-like substance (Wax) may be explained by the increased length of the thicker needle. The 27 gauge needle was ¼ inch (6mm) longer than the 30 gauge needle producing increased "springiness". This could account for the observed greater bending of the needle. Irrespective of differences between the different needle sizes, all needles demonstrated a significant reduction in deflection with the bi-directional rotation insertion technique.

The study design always tested linear insertion followed by rotational insertion. Maintaining this order of needle insertions was believed to minimize bias produced from a dulling or deforming of the needle. The authors are aware that a random order between

different techniques might have been selected. Each of the two study designs has its own merits.

The use of a bi-directional rotation insertion technique becomes clinically significant when performing injections such as the inferior alveolar nerve block. It has been reported in the literature that anywhere from 18% to 25% of inferior alveolar block injections result in unsatisfactory anesthesia[19,20]. This study has demonstrated that a needle that traverses 20 mm of a tissue-like substance can deflect as much as 5 mm. The bi-direction rotation insertion technique provides greater accuracy of placement for those injections which require deep needle penetration. Closer placement of the needle tip to the intended target may reduce the incidence of anesthetic failures. This hypothesis requires a prospective clinical study.

Superficial injections such as the palatal or supra-periosteal injection may not be substantially altered by this technique. However, it is worthy to note, the authors found that tissue resistance to all needle penetration was diminished with the use of a bi-directional rotation technique. This suggests that needle penetration forces are also reduced with the use of rotational insertion. This anecdotal finding will require further investigation to determine its validity.

Conclusion:

The success of a local anesthetic injection is multi-factorial. An understanding of issues which affect this outcome are important to all clinicians. Needle deflection is one factor which plays a major role in achieving predictably successful anesthesia. This study was conducted to clarify this cause and effect relationship between the needle and deflection. The following conclusions are offered:

1. The factor which most greatly affects the path taken through a tissue-like substance by an eccentric beveled needle are the force vectors which act upon the beveled surface.
2. The use of a bi-directional rotation insertion technique minimizes needle deflection, resulting in a straighter tracking path for 30, 27 and 25 gauge dental needles.
3. The use of a bi-directional rotation insertion technique minimizes needle deflection in the three different tissue-like substances tested in this study.

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[13] Robinson, S.F., Mayhew, R.B., Cowan, R.D., Hawley, R.J., Comparative study of deflection characteristics and fragility of 25-, 27-, and 30-gauge short dental needles. JADA 109:920-924, 1984.
[14] Aldous, J. Needle deflection: a factor in the adminstration of local anesthetics. JADA 77:602-604, 1968.
[15] Robinson, S.F., Mayhew, R.B., Cowan, R.D., Hawley, R.J., Comparative study of deflection characteristics and fragility of 25-, 27-, and 30-gauge short dental needles. JADA 109:920-924, 1984.
[16] Jeske, A.H., Boshart, B.F., Deflection of conventional versus nondeflecting dental needles in Vitro. Anesth Prog March:62-64, 1985.
[17] Jeske, A.H., Boshart, B.F., Deflection of conventional versus nondeflecting dental needles in Vitro. Anesth Prog March:62-64, 1985.
[18] Aldous, J. Needle deflection: a factor in the adminstration of local anesthetics. JADA 77:602-604, 1968.
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Research study: "In-Vitro study of needle deflection: A linear insertion vs. bi-directional rotation insertion technique."

Figure Legends

1. Figure 1: Customized Dental Surveyor with fabricated radiographic jig and tissue-like substance container.
2. Figure 2: Simplistic illustration of vector force system applied to the beveled end of a needle.
3. Figure 3: Vector analysis illustrating a linear path of insertion when a Bi-directional rotation insertion technique is utilized.

Graphs

1. **Wax:** Linear vs. Bi-directional rotation insertion; Paired T-test.
2. **Frankfurter:** Linear vs. Bi-directional rotation insertion; Paired T-test.
3. **Hydrocolloid:** Linear vs. Bi-directional rotation insertion; Paired T-test.

Radiographic Images

1. **30 guage needle:** Example of a 30 gauge needle using the two different techniques of Linear Insertion and Rotational Insertion.
2. **27 guage needle:** Example of a 27 gauge needle using the two different techniques of Linear Insertion and Rotational Insertion.
3. **25 guage needle:** Example of a 25 gauge needle using the two different techniques of Linear Insertion and Rotational Insertion.

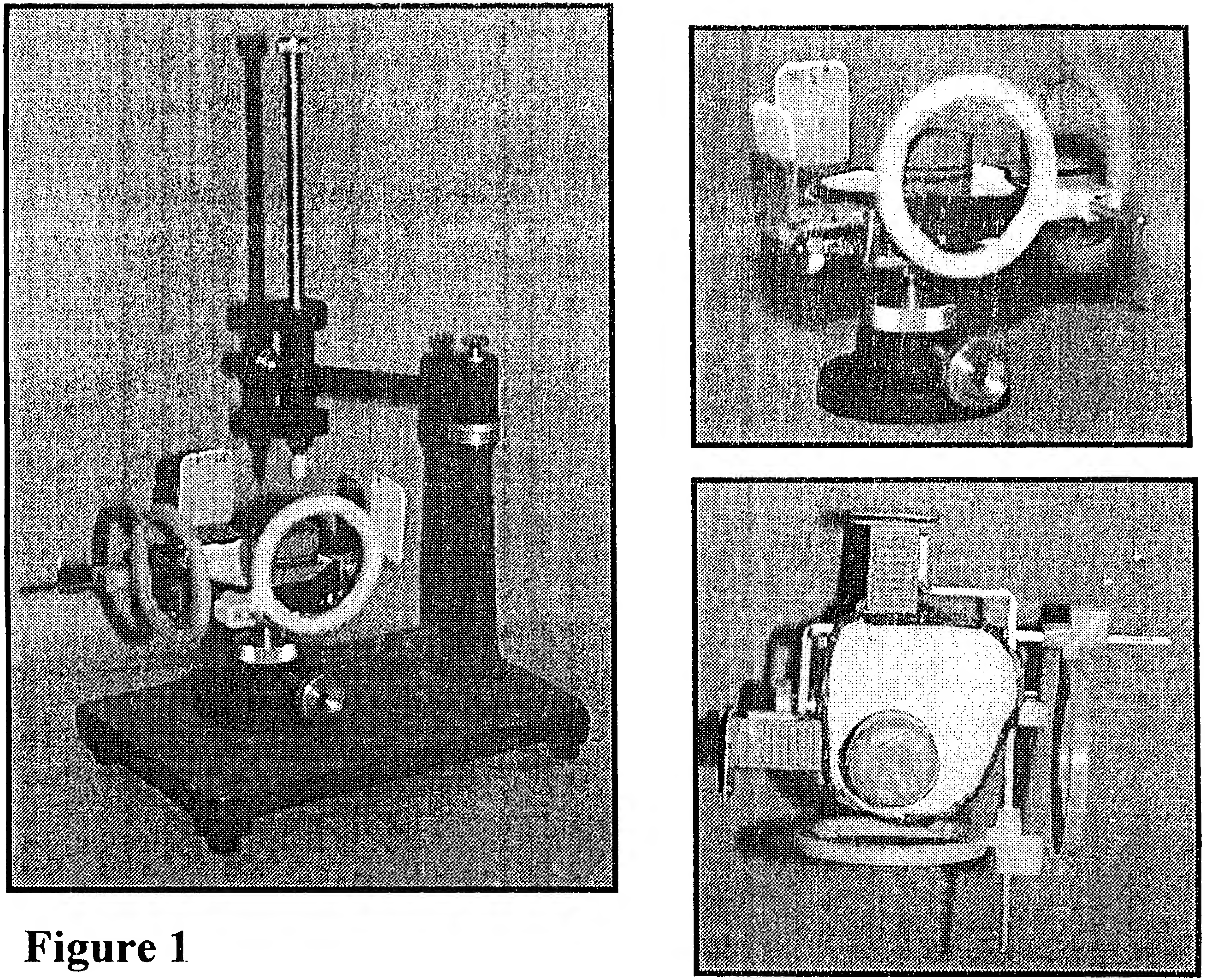


Figure 1

Force Vectors

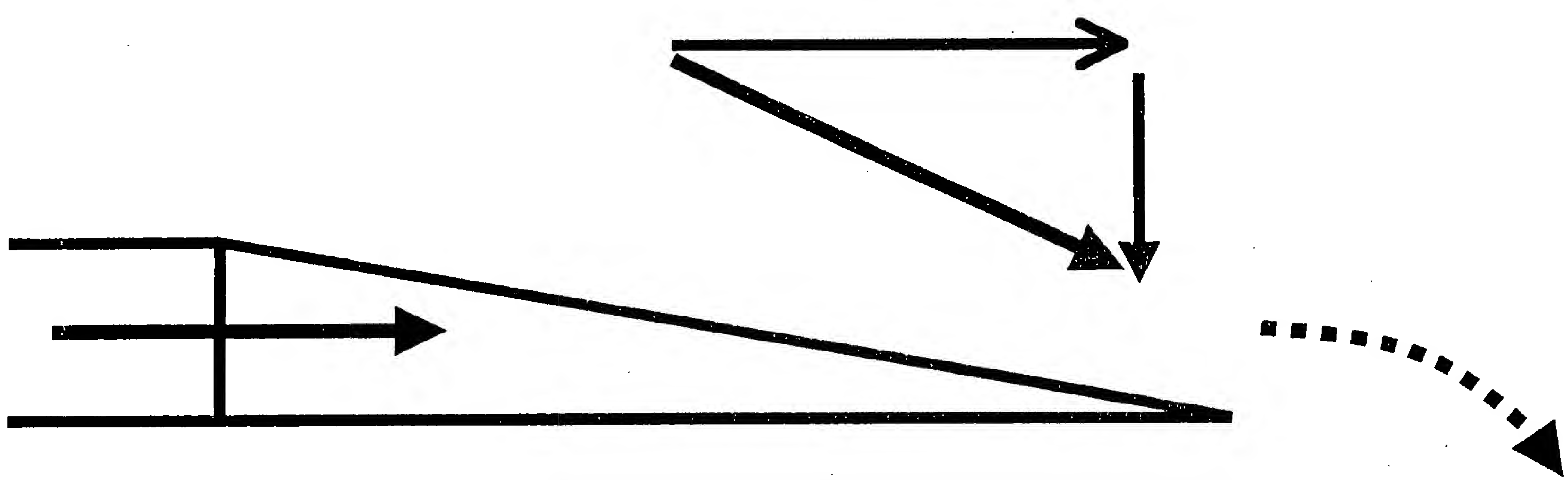


Figure 2

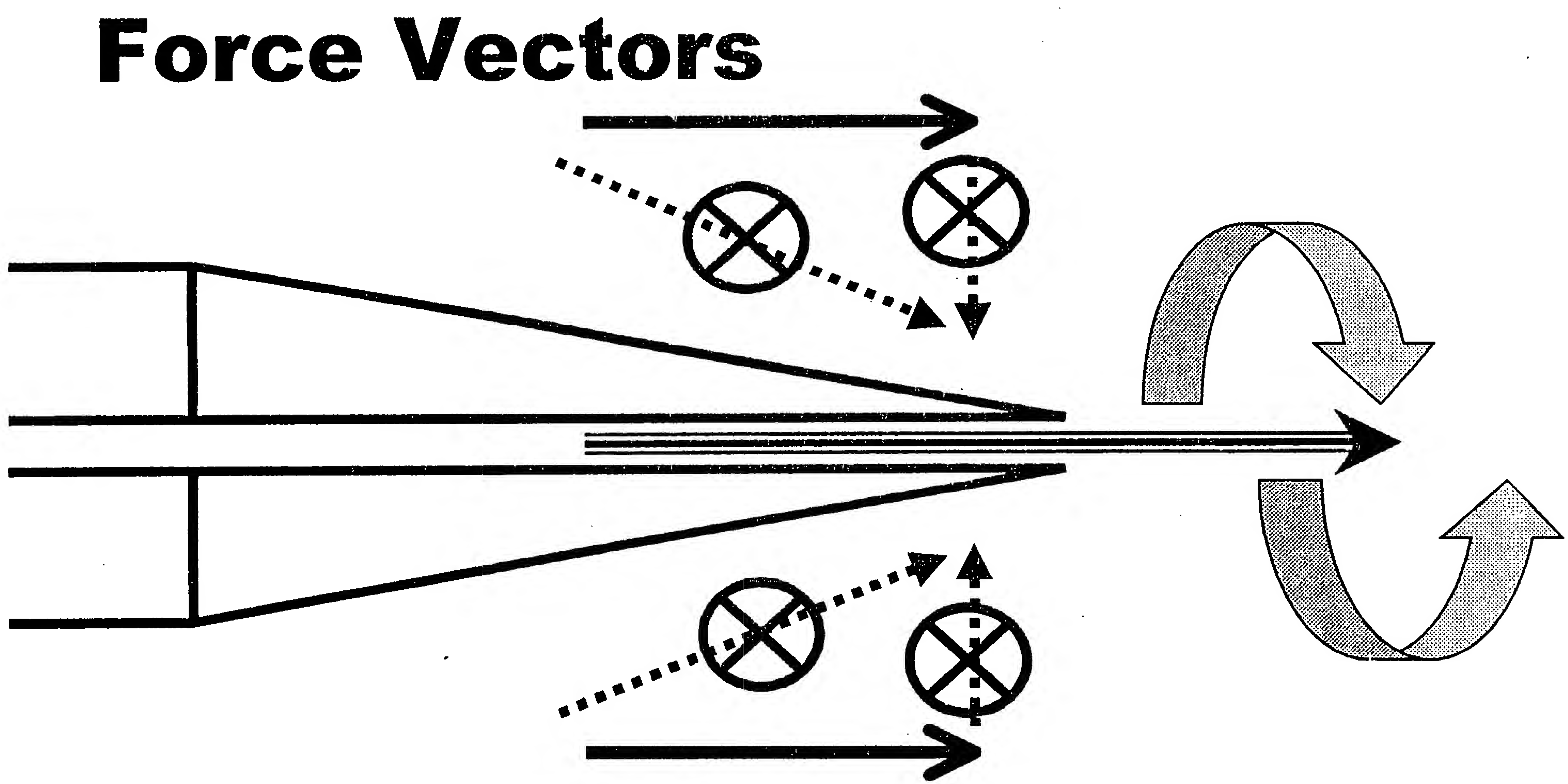
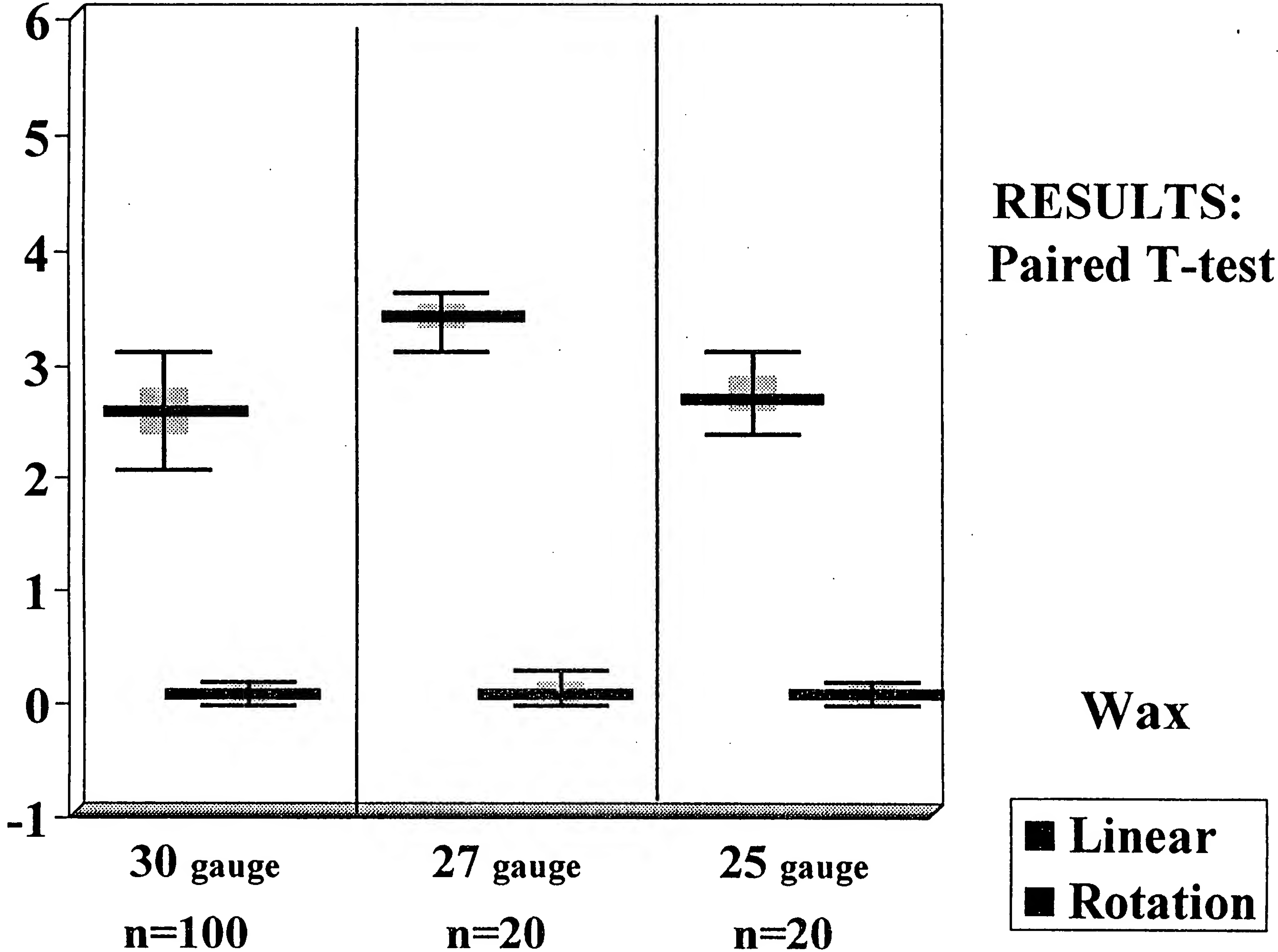


Figure 3

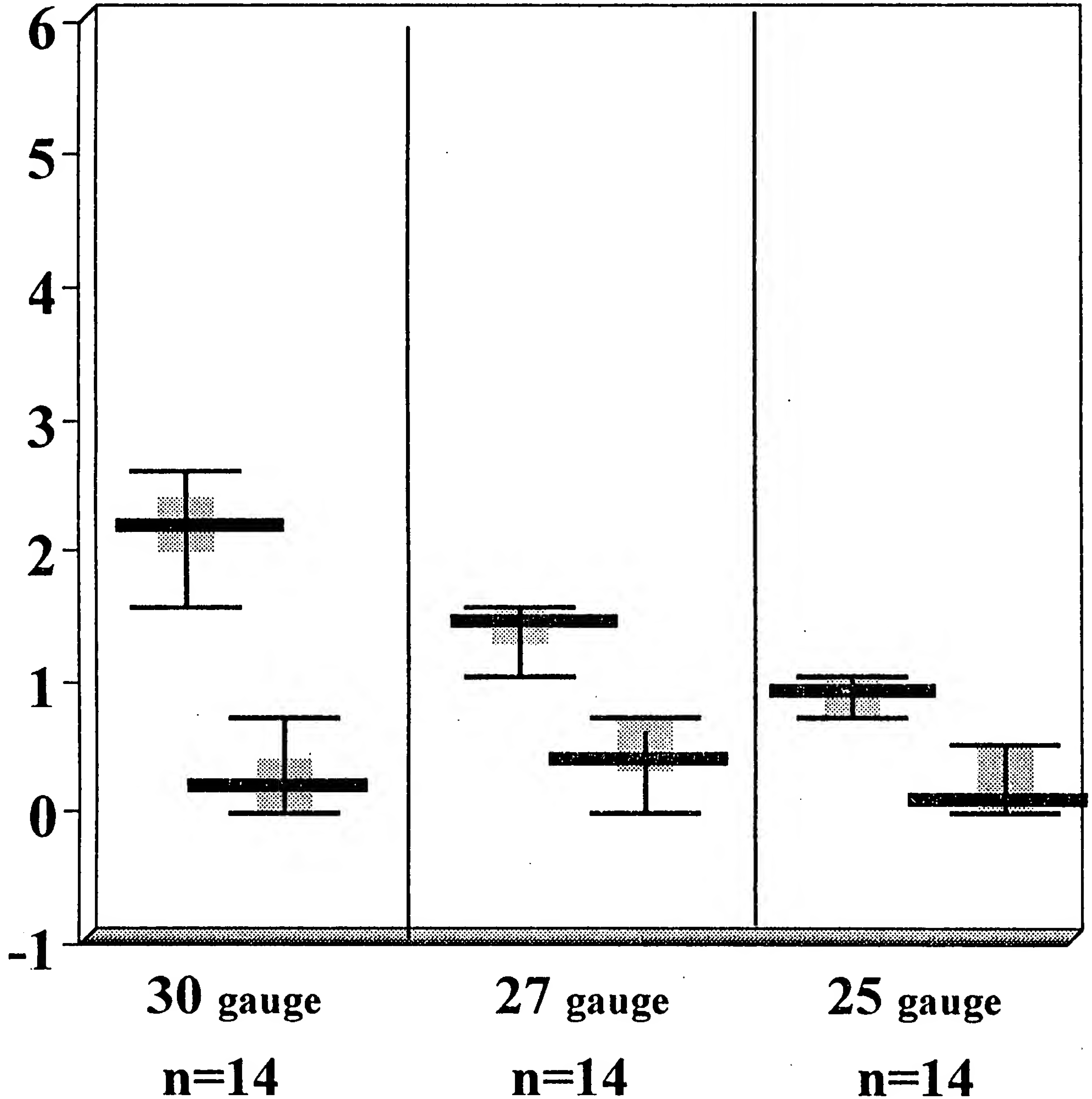
Linear vs. Bi-directional rotation Insertion



RESULTS:
Paired T-test

Wax

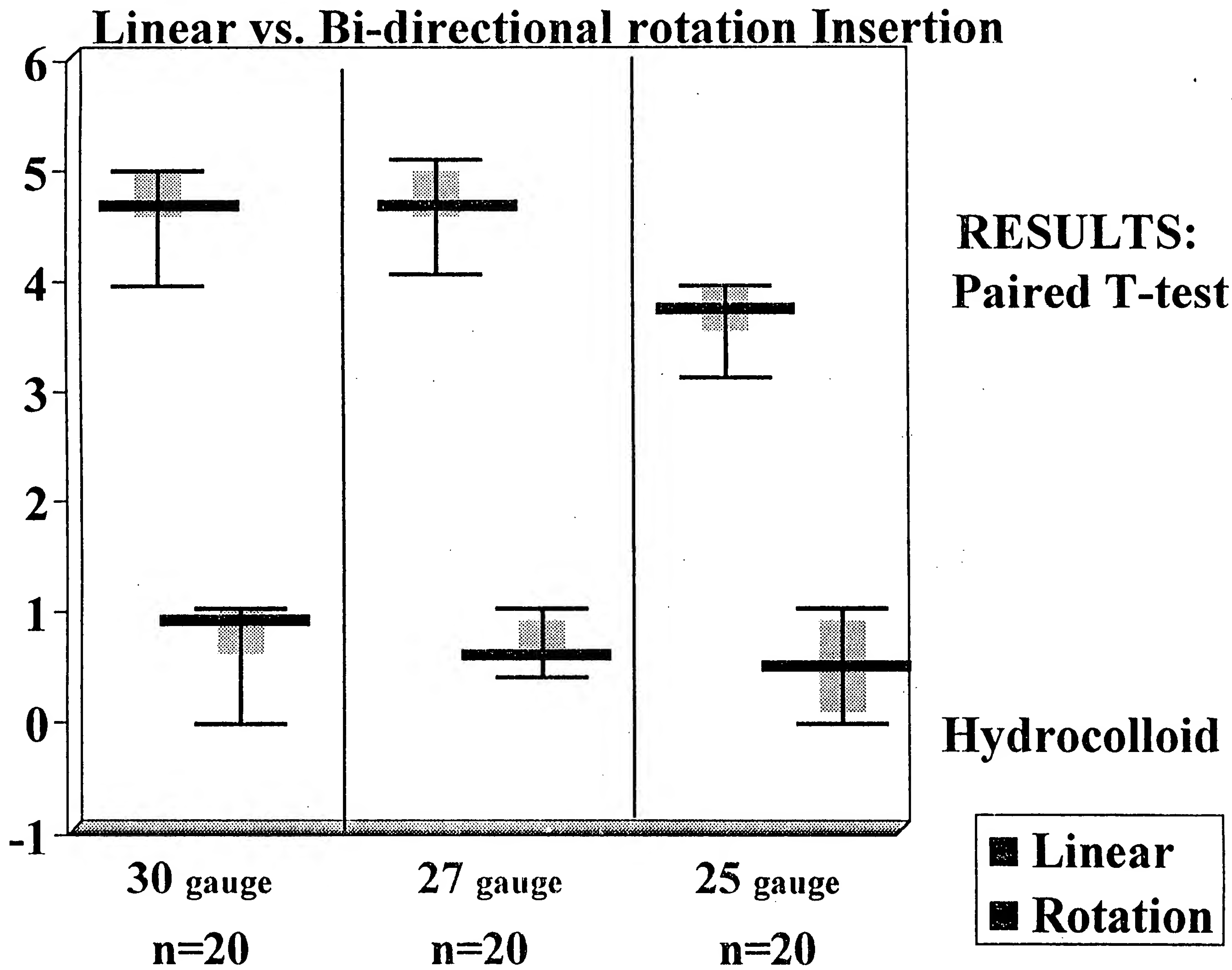
Linear vs. Bi-directional rotation Insertion

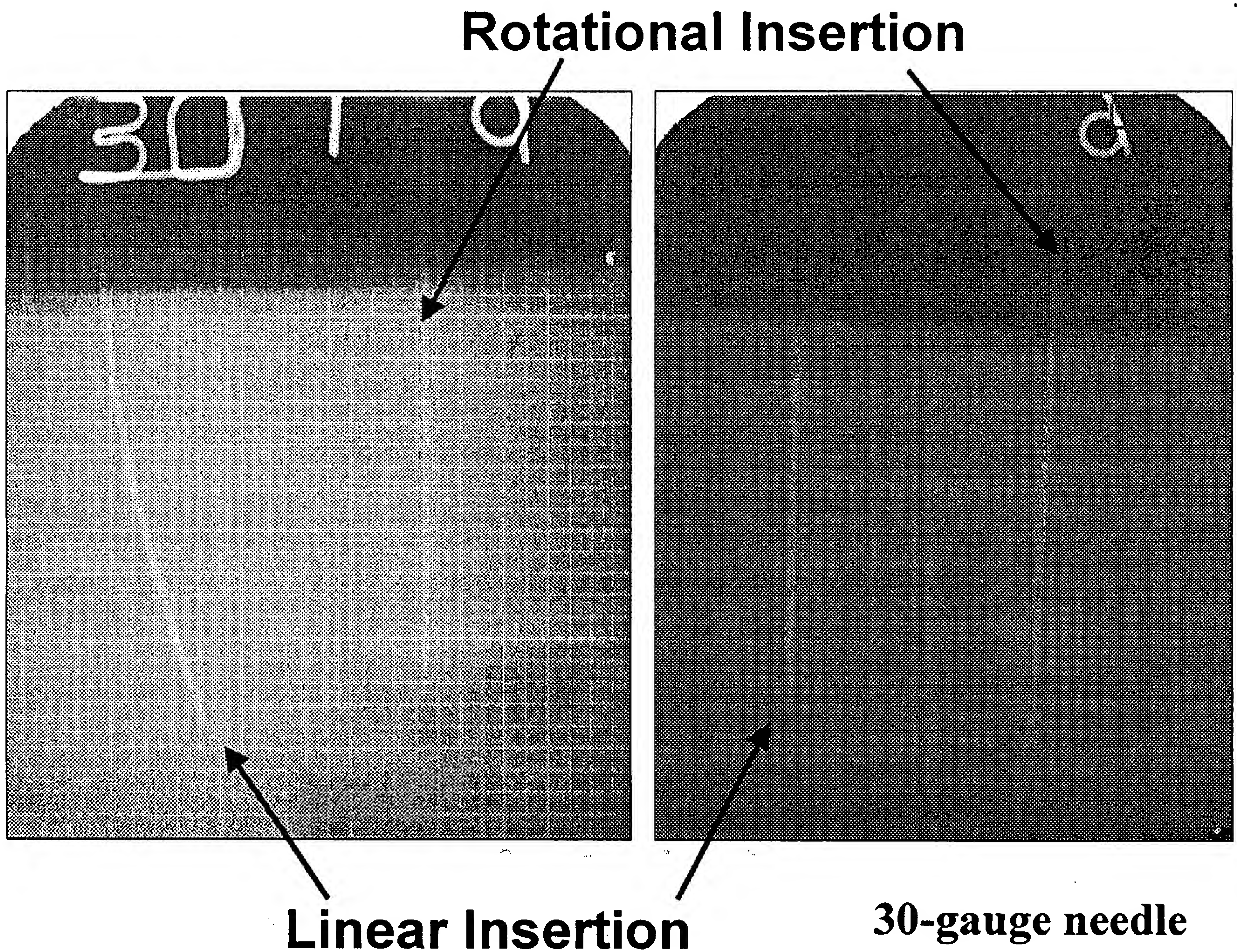


RESULTS:
Paired T-test

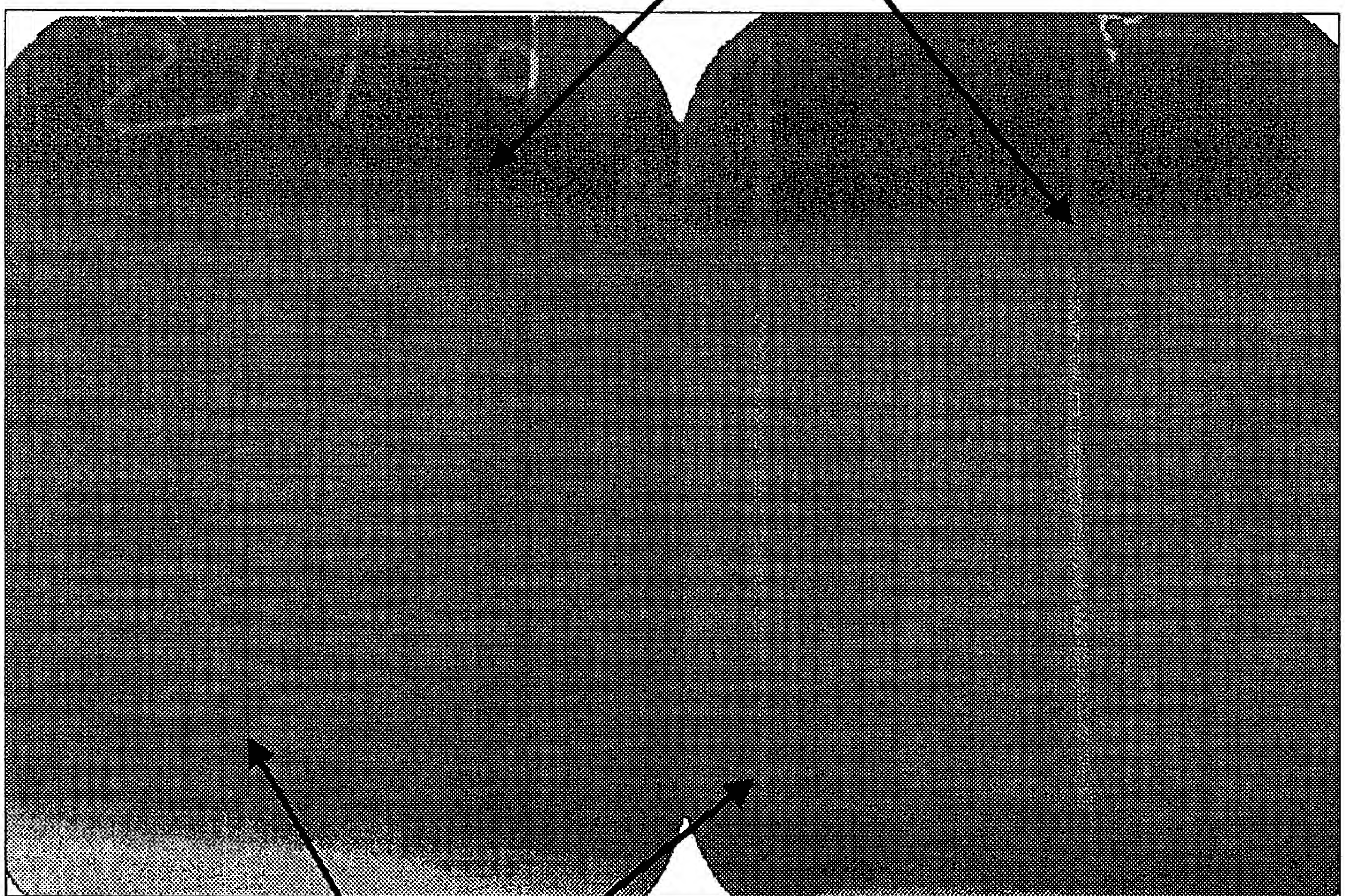
Frankfurter

■ Linear
■ Rotation


Linear vs. Bi-directional rotation Insertion
6
5
4
3
2
1
0
-1
30 gauge
n=20
27 gauge
n=20
25 gauge
n=20
RESULTS:
Paired T-test
Hydrocolloid
Linear
Rotation

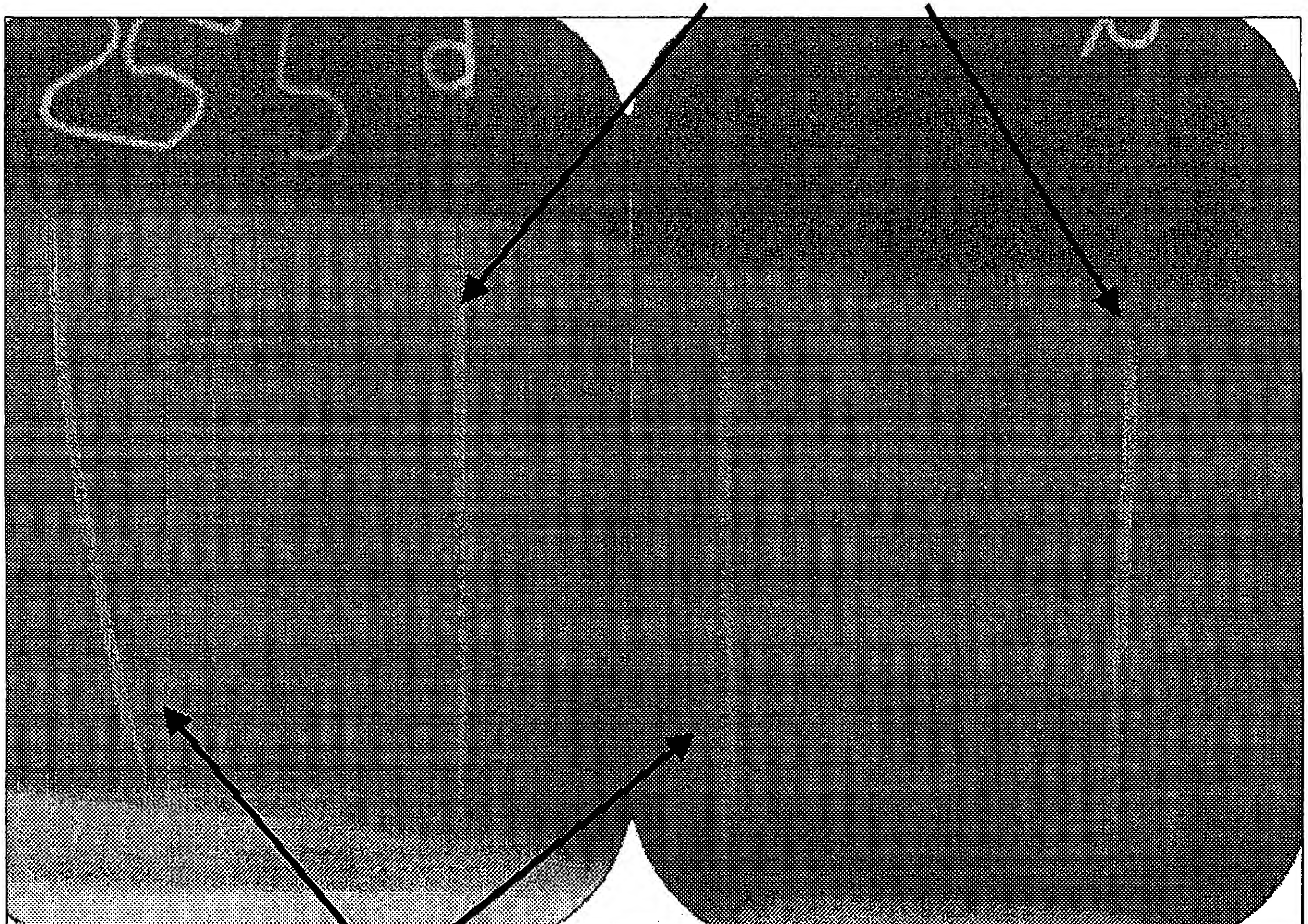


30-gauge needle



27-gauge needle

Rotational Insertion



Linear Insertion

25-gauge needle

Continuing education questions

1. Which of the following factors is <u>not</u> related to the failure to achieve successful dental anesthesia.
    a) Patient anatomical variations.
    b) Improper operator technique.
    c) Needle deflection.
    d) Type of local anesthetic selected.

2. The factor which was shown to most greatly influence the magnitude of needle deflection in this study was.
    a) Diameter of the needle.
    b) Length of the needle.
    c) Vector force system on the bevel of the needle.
    d) Metallurgy of the needle.

3. Why has needle deflection been suggested as an important factor in the administration of dental anesthesia?
    a) It may lead to the breakage of the needle.
    b) It has been shown to produce pain if not controlled.
    c) It may produce a slower onset of anesthesia.
    d) It may lead to final needle tip placement at an improper location.

4. The bi-directional rotation insertion technique differs from the traditional technique in which of the following way.
    a) It results in a vector force system in which vertical vectors cancel each other out producing a straighter movement of the needle.
    b) It results in a vector force system in which the horizontal vectors cancel each other out producing a straighter movement of the needle
    c) It results in slower linear action that produces a straighter movement of the needle.
    d) It can only be performed with a specially designed needle.

Answers:
1. d
2. c
3. d
4. a

Exhibit B

Quintessence International

Editor-in-Chief: William F. Wathen, DMD

August 2, 1999

Mark N. Hochman, DDS, FAGD
26 Meadow Woods Road
Lake Success, NY 11020

Dear Dr. Hochman:

I am pleased to inform you that your manuscript, **"In vitro study of needle deflection: A linear insertion vs. bi-directional rotation insertion technique,"** can be considered for publication in *Quintessence International* **pending the authors' attention to the enclosed reviewers' comments**. All reviews are carried out blindly and, because of this, some reviewers may feel free to be more critical than if they knew the origin of the paper. Please remember, however, that the purpose of review is ~~to~~ improve your paper, and reviewers' comments should not be taken personally.

I am returning all materials at this time, and I look forward ~~to~~ receiving your revisions as soon as possible. Please return **two** copies of the revised manuscript, along with the original illustrations (color and/or B/W slides) and two print copies of the illustrations, to my editorial coordinator:

Ms. S. Sharmayne Bierschenk
~~Center for Professional~~ Development
Baylor College of Dentistry
3302 Gaston Avenue
Dallas, Texas 75246
214/828-8286 fax
e-mail: sbiersch@ont.com

If we do not receive your revised manuscript by **September 7, 1999**, it will be assumed that you have decided to withdraw it from consideration.

Thank you for once again for considering *Quintessence International*.

Sincerely,

William F. Wathen, DMD
Editor-in-Chief

enclosures
Log # 99430

Center for Professional Development, Baylor College of Dentistry
3302 Gaston Avenue, Room 610
Dallas, Texas 75246
Fax: (214) 828-8286 • e-mail: wathen@ont.com

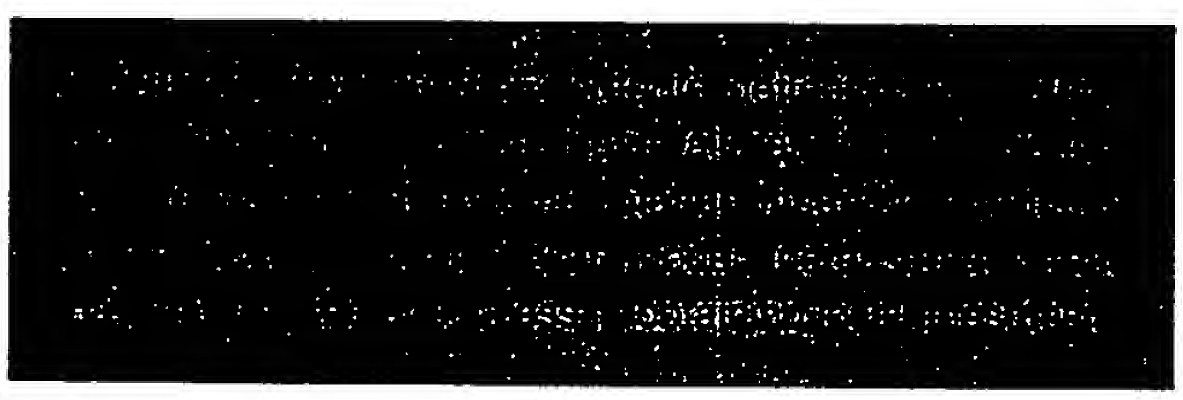
Exhibit C

In vitro study of needle deflection: A linear insertion technique versus a bidirectional rotation insertion technique

Mark N. Hochman, DDS*/Mark J. Friedman, DDS**

Method: Deflection of dental needles during tissue penetration has been associated with a failure to achieve successful anesthesia. The purpose of this study was to determine whether needle deflection in a tissuelike substance could be minimized through the use of a bidirectional rotation insertion technique. **Method and materials:** Three in vitro deflection test models were constructed, each incorporating a different tissuelike substance of a different density. Each substance was tested with 3 different needle sizes (30-gauge, 27-gauge, and 25-gauge). A customized dental surveyor allowed for standardized needle insertions to a standardized depth of 20 mm. Two different insertion techniques, a linear insertion technique and a newly described bidirectional rotation insertion technique, were tested. Radiographic analysis was performed after each insertion. **Results:** The bidirectional rotation insertion technique described was consistently more effective in minimizing needle shaft deflection for 30-g, 27-g, and 25-gauge needles. The differences were statistically significant. Each of the different tissuelike substances consistently demonstrated this reduction in needle deflection. **Conclusion:** The factor that most greatly affects the path taken by a needle through a tissuelike substance is the force vector that act on the needle's beveled surface. The use of a bidirectional rotation insertion technique minimized needle deflection, resulting in a straighter tracking path for 30-, 27-, and 25-gauge dental needles, in 3 different tissuelike substances tested in this study. (Quintessence Int 2000;31:xxx–xxx)

Key words: computer-controlled drug delivery system, deflection, force penetration, insertion technique, local anesthesia, needle



Successful local anesthesia is critical to the daily practice of dentistry. It is a prerequisite to ensure maximum patient comfort while a wide variety of clinical procedures are performed on the hard and soft tissues of the oral cavity. Therefore, achieving predictable results in local anesthesia is of great importance to all clinicians. Failure to do so can lead to increased stress for both the operator and the patient.[1,2] An injection that is recognized as one of the more difficult in dentistry is the inferior alveolar nerve block.[3] A number of physical factors have been associated with the relative success or failure of the inferior alveolar nerve block. They include anatomic variations between patients, operator technique, and needle deflection.[4,5]

Contemporary dental anesthesia textbooks indicate needle deflection as a source of anesthetic failures.[4,5] It has been reported that the rate of failure for inferior alveolar nerve block can range from 20% to 30%, and most dentists have experienced some difficulty with this injection.[4–8] The inferior alveolar nerve is contained within the pterygomandibular space. For a needle tip to be in close proximity to the intended target, it must penetrate a variety of tissue types, including mucosa, buccinator muscle, submucosal connective tissue, fat, and the termporopterygoid fascia.[9]

The needle initiates its path when it first enters through the buccal mucosa at a point between the pterygomandibular raphe and temporal crest of the mandible ramus. The mucosa should be held firmly in

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place during insertion to ensure precise needle entry. The standard technique requires needle penetration of the buccinator muscle and fascia. As the needle advances, it will traverse the connective tissue and adipose tissue found within the pterygomandibular space. The final intended target for the needle is the mandibular foramen, found distal and inferior to the mandible lingula.[8] All these tissue layers offer varying degrees of resistance to needle penetration.[9] The entire inferior alveolar neurovascular bundle has a diameter of approximately 2.2 mm, and the pterygomandibular space has a total estimated volume of only 2 mL.[10] Even a small deviation from the intended target may have a negative effect on the success of an inferior alveolar nerve block.[11]

The most widely accepted model for studying needle deflection is an in vitro model that utilizes tissuelike substances. This design provides a reliable testing environment without the need for human tissues. Experimentation of this type eliminates many of the difficult ethical questions raised by animal studies. The clinical relevance of a needle deflecting through an analog model to the human condition has been previously established.[12-15] It has been demonstrated that this type of testing provides valuable insight into needle characteristics in a experimental setting.[16-19]

Needle diameter (gauge) and the relative flexibility or resilience of the needle shaft are the physical characteristics reported to affect needle deflection.[13] Early studies focused primarily on static shaft flexibility and did not take into account any of the vector forces generated on the needle's bevel during movement.[13-19] These studies concluded that shaft diameter is the most critical factor affecting bending or deflection of the needle.[13-19]

Aldous[17] was the first to investigate needle deflection with a dynamic testing method that might more accurately portray clinical conditions. He incorporated the use of a dental surveyor that standardized the direction of the injection force. He selected materials of uniform densities to serve as tissuelike simulations. The actual path and degree of needle deflection was recorded on radiographic films after the needle was inserted in the test material. Aldous[17] concluded that the relative degree of needle deflection is inversely proportional to the needle shaft diameter. He also stated that the shape and angle of the bevel affect the degree of deflection.

Robinson and coworkers[18] expanded Aldous's original investigation to measure needle deflection geometrically in 2 spatial planes. Radiographs were taken at perpendicular angles, allowing a more precise analysis of needle deflection. They concluded that all needles produce a path of deflection and that the degree of deflection cannot be correlated to the gauge of a needle. Robinson et al[18] suggested that deflection is related more to the type of alloy used for manufacture of the needle than to the gauge.

Jeske and Boshart[19] tested a unique needle design (Tru-ject Cannulae) using the same testing model described by Aldous.[17] The needle they tested was beveled on 2 opposite sides of the shaft, placing the needle tip at approximately the center of the long axis. They concluded that needle tip design is more critical to reducing and eliminating deflection than is the diameter of the needle.

Controversy in the literature exists regarding the factors responsible for needle deflection. This study was conducted to determine if use of a new bidirectional rotation insertion technique could minimize needle deflection. A second objective of the study was to determine if the gauge of the needle had an effect on the amount of deflection when bidirectional rotation insertion was used. A final objective was to determine which factors had the greatest influence on the magnitude of needle deflection.

METHOD AND MATERIALS

Bidirectional rotation insertion technique

A new needle insertion technique has been designed to overcome the undesirable effect of needle deflection. This technique seeks to produce a more accurate, straight-line needle tracking through substances, regardless of needle gauge. The technique relies on a penlike grasp that makes it possible to rotate a needle in a back-and-forth manner. The needle is rotated between the thumb and index finger 180 degrees in each direction. The type of rotation used is analogous to techniques that have been described for endodontic file instrumentation and acupuncture.[20,21] The purpose of the bidirectional rotation is to neutralize the force vectors that act on the needle bevel and bend the needle shaft. This bidirectional rotation action is maintained during the entire course of needle advancement.

Deflection tests

The testing protocol for the study followed the design set forth by Robinson et al.[18] Three deflection tests models were constructed. The test models differed in the tissuelike substances that were used. The following materials served as tissuelike substances in this study: hydrocolloid, (test model A), frankfurters, (test model B), and soft bite-wafer wax (test model C). For each tissuelike substance, 3 different-sized needle gauges were tested: 30-gauge 1.25-inch, 27-gauge 1.25-inch, and 25-gauge 1.25-inch (Monojet Ultra Sharp Model

400, Sherwood Medical).

In each of the 3 models, the needle was inserted to a depth of 20 mm. This standardized working length was selected because of the availability of the 30-gauge 1.00-inch (25.4-mm) needle. All 3 tests employed a modified dental surveyor (Ney) to produce standardized needle insertions (Fig 1). Traditional screw-on needle hubs were attached to a customized arm of the surveyor. The needle was then advanced into the tissuelike substance using either the test technique (the bidirectional rotation insertion movement) or the control technique (the traditional insertion with a linear nonrotational movement). A sufficient number of tests were performed for each needle within a substance to provide adequate statistical relevance.

Test model A. For the first deflection test model, hydrocolloid (Acculoid Extra Strength, Van R Dental) was placed into a 6-oz plastic container that fit into the custom surveyor jig. The jig was constructed to produce consistent, perpendicular angulation of the x-ray tube head. The custom jig was designed to record needle deflection in 2 planes of space fixed at 90 degrees from one another (see Fig 1). This enabled the total amount of deflection to be calculated from an algebraic formula. A total of 60 insertions were performed with 30 needles (10 needles for each needle gauge size).

Each needle served as its own control between the 2 techniques. The needle was first inserted into the tissuelike substance with a linear nonrotating movement. The same needle was then inserted into the test material with the bidirectional rotation insertion technique. After the needle was used for the second insertion technique, it was discarded and the test was repeated with a new needle.

After each needle insertion, 2 x-ray films were exposed at 15 mA, 65 kV(p), 10 impulses, and then developed. A metallic x-ray grid was used to record the maximum amount of deflection produced. Each film was measured with a Boley gauge on a superimposed grid from the point of insertion to the tip of the needle. The total amount of deflection produced was calculated using a geometric principle described by Robinson and coworkers.[18]

Test model B. A second deflection test was performed on processed meat, frankfurters (Hebrew National). The protocol used in the first test model was followed. A total of 42 insertions were performed with 21 needles (7 needles for each needle gauge size, 30-, 27-, and 25-gauge).

Test model C. A third deflection test was performed on soft bite-wafer wax (Hygenic). A custom platform was constructed to align the wax parallel to the long axis of the needle held by the dental surveyor arm. The use of soft bite-wafer wax allowed visual inspection to measure and determine the amount of needle deflection.

Fig 1 Customized dental surveyor with fabricated radiographic jig and tissuelike substance container.

The needle bevel was oriented perpendicular to the surface of the wax; this was confirmed by the operator, who was wearing x2.5 magnification loops (Designs for Vision). The needle was first inserted in the wax with a nonrotational linear movement, to a depth of 20 mm. The wax was marked at a point where the needle tip ended in the wax to identify the deflection. The needle was removed from the wax and positioned in front so that the needle shaft was aligned to the access hole created from the initial insertion. A Boley gauge was used to measure the distance of deflection that was observed.

The same needle was employed for the second test, the bidirectional rotation insertion technique. Each needle therefore served as its own control. A total of 100 insertions were performed with 50 needles of a 30-gauge size. An additional 40 insertions, with 10 27-gauge and 10 25-gauge needles, was conducted to compare the 2 techniques. The needles used for this study were randomly selected from a standard box of 100 needles, supplied by a local dental distributor.

RESULTS

The study design involved repeated sets of 3 experiments comparing needle deflection for the 2 techniques of needle insertion for a particular needle gauge in different injection medias. Statistical data analysis involved paired *t* tests for each experiment. The rotation insertion technique was consistently more effective than linear insertion in minimizing and eliminating needle shaft deflection for 30-, 27-, and

TABLE 1 Needle deflection in 3 test substances

		Linear insertion (mm)			Rotation insertion (mm)		
Material	Needle size	M an	SD	Range	Mean	SD	Range
Hydrocolloid	30-gauge	4.7	0.3	4.0–5.0	1.1	1.4	0.0–0.7
	27-gauge	4.6	0.3	4.1–5.2	0.8	0.2	0.5–1.1
	25-gauge	3.8	0.1	3.2–4.0	0.5	0.2	0.0–0.7
[redacted]							
Wax	30-gauge	2.7	0.3	3.8–2.2	0.1	0.2	0.0–0.2
	27-gauge	3.4	0.5	3.2–3.7	0.1	0.5	0.0–0.3
	25-gauge	2.6	0.4	2.3–3.1	0.1	0.3	0.0–0.2

Statistically significant (P<0.05).

Fig 2 Insertion of a 30-gauge needle with 2 different techniques: linear insertion and rotation insertion.

25-gauge needles (Fig 2). Each of the tissuelike substances tested consistently demonstrated this reduction in needle deflection with the bidirectional rotation insertion technique.

The differences in deflection between linear and rotational insertion techniques were found to be statistically significant ($P < 0.05$) in each of the experiments conducted. A 95% confidence level, with no overlap of the upper and lower limits, was observed.

Mean values for needle deflection with linear insertion and bidirectional rotation insertion are presented in Table 1.

DISCUSSION

It has long been suggested that all needles deflect, irrespective of the diameter of the needle being used. Aldous[17] was the first to devise a dynamic testing method to record deflection, and he concluded that needle deflection is inversely related to needle diameter. Robinson and coworkers[18] investigated deflection, modifying Aldous's model to improve the measuring and recording accuracy. They concluded that all the tested needles deflected, irrespective of gauge. Robinson et al[18] stated that the degree to which needles deflect is not related to diameter shaft but may be related to the specific metals used in manufacture.

A previous study has shown that beveled tip design of a needle will influence the path the needle takes as it penetrates through substances of varying densities.[13] It is apparent that a force system is produced on the needle's beveled surface. This force vector system is the same for any cylindrical object with a beveled end, and it will follow Newton's third physical law of equal and opposite forces.[22] Therefore, an application of a resultant vector force on the beveled surface of an eccentrically pointed cylindrical shaft will produce physical bending (deflection) along the path of insertion (Fig 3). The amount of deflection exhibited by the beveled cylindrical object is determined by the sum of the forces acting on an object in a specific medium.

A bi-beveled needle has the advantage of possessing a needle tip that is centrally located along the needle shaft. Testing of this needle design yielded the expected results of reduced needle shaft deflection.[17,19] The bi-beveled needle eliminates the perpendicular forces that are responsible for needle shaft deflection. However, the most common needle commercially available is an eccentrically pointed beveled needle.[23] Another needle, the Accujet (Astra Pharmaceuticals), enables bevel orientation to be monitored. A visual marker on the needle hub allows the operator to position the bevel in a specific direction. It is thought that

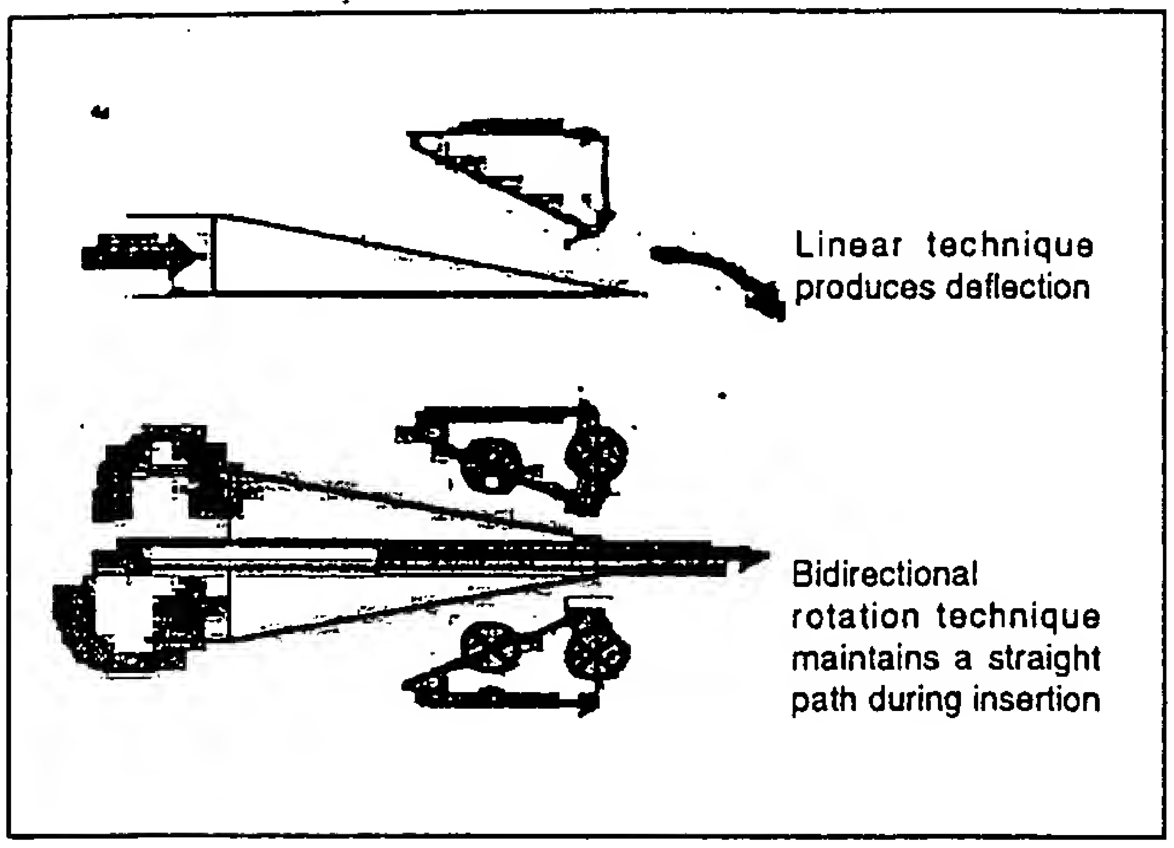

Fig 3 Simplistic illustration of vector force system applied to the beveled end of a needle. Vector analysis illustrating the path taken during needle insertion with the linear insertion and the bidirectional rotation insertion techniques. Yellow aroow = movement of needle; red arrow = final path of needle movement; brown arrow = resultant force vector; blue arrow = vertical force vector; green arrow = forizontal force vector; pink cross = cancelled force vector.

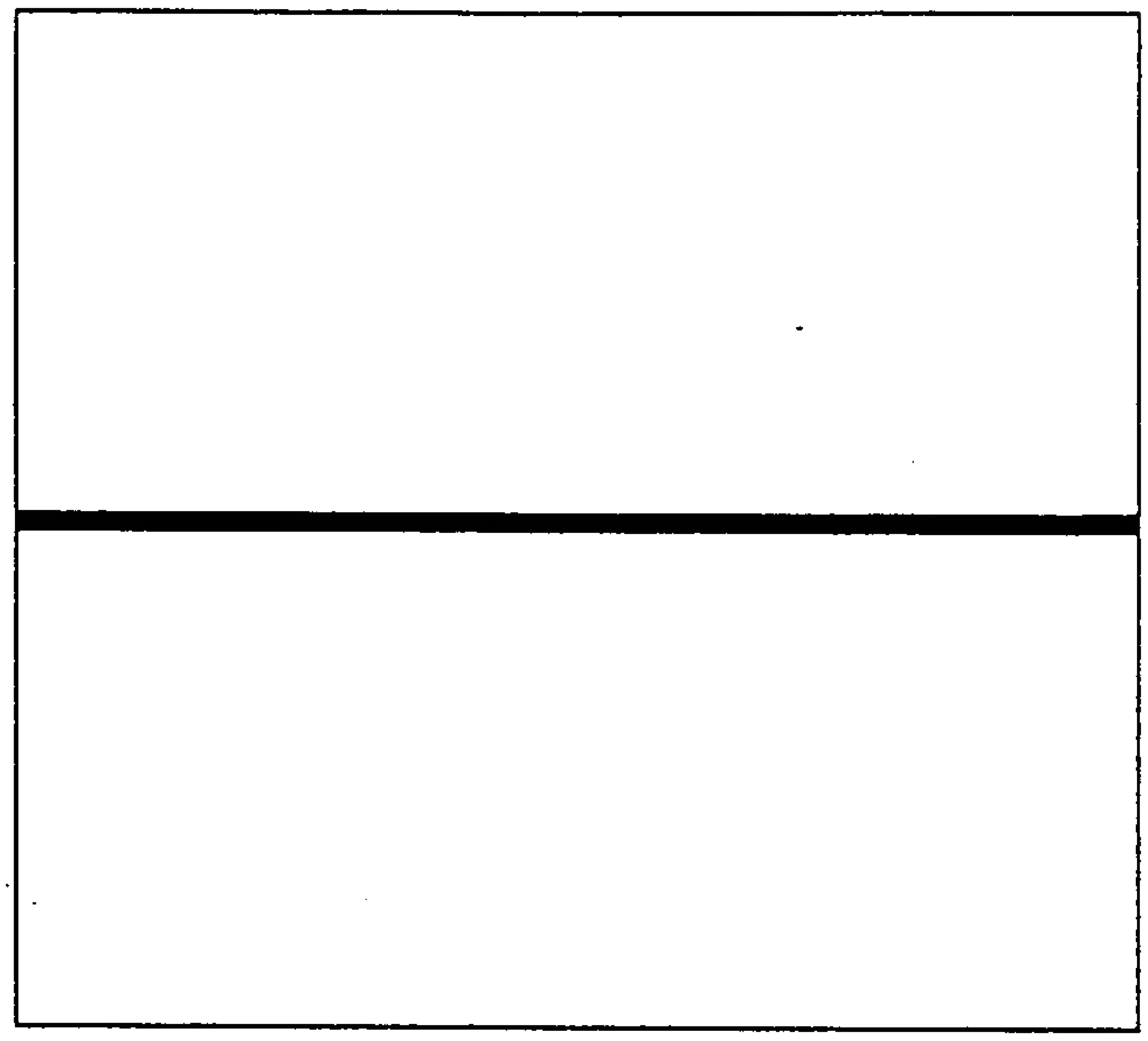

Fig 4 The bidirectional rotation technique is maximized by the use of a penlike grasp *(above)* rather than palm-thumb grasp *(below)*.

this will assist the dentist in better controlling the final needle position. The needles described above require the operator to use a linear insertion technique.

Use of the bidirectional rotation insertion technique, even with an eccentrically pointed beveled needle, allows the operator to cancel out the perpendicular force vectors on the bevel that cause bending along the needle shaft (see Fig 3). This technique generates forces that cause the needle to travel in a linear path. The straight path produced by the bidirectional rotation insertion technique will occur irrespective of needle gauge, bevel design, or the metal alloys used in manufacture.

Berns and Sadove[11] conducted a radiographic in vivo study. Sixty-six inferior alveolar nerve block injections were performed on adult patients. A 22-gauge needle was used to administer a mixture of local anesthetic and radiopaque dye. Cephalometric lateral head films were taken after the needle was inserted to the proper depth and securely positioned in place. The radiographic images revealed bending of a rigid 22-gauge needle at its final position. The authors stated that the needle tip should be no more than 0.5 cm from the mandibular foramen. They concluded that the closer the needle tip is placed to the mandibular foramen, the more likely the success of the inferior alveolar nerve block. The study supported the observation that there is a direct correlation between a positive clinical outcome (ie, anesthesia) and the positioning of the needle tip. The study documented radiographic evidence of in vivo needle deflection. It is therefore not unreasonable to infer that needle deflection affects the final needle tip position, thus affecting clinical success.

In addition to reducing needle deflection, the bidirectional rotation insertion technique seems to substantially reduce the force required to penetrate a substance. Preliminary data suggest that a reduction of force penetration in the range of 40% to 50% can be anticipated when this technique is used. This may prove to be particularly beneficial for those injections that penetrate dense connective tissue, for example, the palatal tissue of the oral cavity. Additional investigation is warranted to determine the clinical implications of these findings.

The traditional handheld syringe requires a palm-thumb grasp (Fig 4) and does not lend itself easily to the rotational insertion technique. This may explain why the technique has not been described in the past. A recently introduced anesthetic delivery system (The Wand, Milestone Scientific) was designed to use a lightweight, disposable, penlike handpiece requiring the operator to use a thumb and index finger grasp (see Fig 4). The benefits of a bidirectional rotation insertion technique can be maximized with this penlike grasp.

The density of the substance in which a needle is inserted appears to influence the amount of deflection produced by the bevel. In this study, the tissuelike sub-

stance with greatest density, (ie, hydrocolloid) consistently produced greater deflection than did less dense substances. Entry in a fluid-filled compartment would minimize deflection because of the fluid viscosity. The oral cavity is primarily composed of tissues with a broad spectrum of densities.

In the testing model, it was critical to provide a consistent and uniform material to eliminate variations between specimens. Three different types of materials were tested, reflecting a range of densities. There are no published studies quantifying the densities of oral tissues in the infratemporal fossa. The materials selected offered a reasonable spectrum analogous to tissues that might be encountered in vivo.[13,17,18] Results indicated that the type of insertion technique used had the greatest influence on the amount of deflection produced, irrespective of the density of the substance tested.

Needle length appears to be another factor that influences the amount of deflection. The standard testing distance of 20 mm was selected in this study based on the commercial availability of a 30-gauge, 1.00-inch needle. Insertion distances of 25 mm and more are typical for the inferior alveolar nerve block. It would be expected that these greater distances would result in greater rates of deflection. Longer needles that travel greater distances would demonstrate larger amounts of bending than were observed in this study. This would only accentuate this study's findings.

The increased length of the thicker needle can explain the finding that needle deflection of 27-gauge needles was greater than that of 30-gauge needles in the denser tissuelike substance (wax). The standard 27-gauge needle is 0.25 inch (6 mm) longer than the 30-gauge needle, producing increased "springiness." This could account for the greater bending of the needle that was observed. Irrespective of differences among the different needle sizes, all needles demonstrated a significant reduction in deflection with the bidirectional rotation insertion technique.

In this study, linear insertion was always tested before rotation insertion. Maintenance of this order of needle insertions was believed to minimize bias produced through dulling or deforming of the needle. A random order between different techniques could have been selected. Each of these possible study designs has its own merits.

The use of the bidirectional rotation insertion technique may become clinically relevant for injections such as the inferior alveolar nerve block. Clinically, the authors have observed a reduction in failed inferior alveolar nerve block injections, as well as a quicker onset of anesthesia with its use. These findings are anecdotal. Future research should be conducted to determine the actual clinical benefits of this technique. This study has demonstrated that a needle that traverses 20 mm of a tissuelike substance can deflect as much as 5 mm. The bidirection rotation insertion technique provides greater accuracy of placement for those injections that require deep needle penetration.

For injections in the palate or other supraperiosteal infiltration injections, high-level accuracy may not be necessary to achieve successful anesthesia. However, it is noteworthy that all needle penetrations required reduced force when the bidirectional rotation technique was used. This suggests that the needle penetration force may be reduced by the rotation insertion technique. This hypothesis requires further investigation to determine the validity of these statements.

CONCLUSION

The success of local anesthesia in dentistry is multifactorial. One of the most challenging of all local anesthesia injections is the inferior alveolar nerve block. Not all anesthetic failures are related to needle deflection. However, needle deflection has been identified as 1 of the elements that can reduce the accuracy and predictably of the inferior alveolar nerve block. This study was conducted to investigate the cause-and-effect relationship between the needle and deflection:

1. The factor that most greatly affects the path taken by an eccentrically beveled needle through a tissuelike substance is the force vectors that act on the beveled surface.
2. The use of a bidirectional rotation insertion technique minimized needle deflection, resulting in a straighter tracking path for 30-, 27-, and 25-gauge dental needles.
3. The use of a bidirectional rotation insertion technique minimized needle deflection in the 3 different tissuelike substances tested in this study.

Further investigations are necessary to determine if the in vitro results will translate to clinical benefits for the inferior alveolar nerve block and other deep-penetrating injections that require accuracy.

ACKNOWLEDGMENTS

The authors would like to thank Dr Eugene Hittleman, Associate Professor and Director of Behavior Science Programs at New York University, College of Dentistry, for his generous effort in providing the data analysis and interpretation of the statistical findings.

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